

Change Notice No.	Notification date	Implementation date
CN/A/22/003	June 17, 2022	July 17, 2022

Subject: Change in the design of septum for sampling port needle used in mdi Single Use Assemblies, ASESS Sampling Systems, and Single Use Components.

Scope: This change notification will affect the products with following catalog numbers: (X can be any alphabet or numeral):

- AXXXXXXXXXXXXXXXXX
- SSXXXXXXXXXXXXXXXXXX

Background:

The sampling port is an integral part of the ASESS sampling system and the sampling port needle allows to draw samples by piercing the sampling port septum. The design of the sampling port septum has been improved to effect easy piercing by the sampling port needle.

Need for Change:

The sampling port needle is pushed through the sampling port septum to provide an aseptic pathway for sampling, and the force required to pierce the sampling port septum is very high and strenuous for the user.

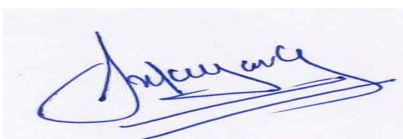
How Does It Affect the User:

From the user point of view, the change shall result in easier piercing of sampling port septum without impacting the quality of the product. All performance specifications, product attributes, material of construction, and traceability shall remain the same.

Effective Date:

mdi sampling port septum, manufactured after the implementation date (July 17, 2022) will have the said changes.

In case you have any queries, please feel free to contact our Technical Support Team at 'info@mdimembrane.com'.



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